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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/903,770 | 07/13/2001 | Bettina Moeckel | 203979US0X | 1467 |

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| EXAMINER | |
|---|---|
| FRONDA, CHRISTIAN L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | 22 |

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/903,770 | Applicant(s) Moeckel et al. |
|---|---|---|
| | Examiner Christian L. Fronda | Art Unit 1652 |

-- *The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *53-82* is/are pending in the application.

4a) Of the above, claim(s) *70, 71, and 73-80* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *53-69, 72, 81, and 82* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Jul 13, 2001* is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 4, 2003 (Paper No. 21) has been entered.

2. Applicants' cancellation of claims 1-4, 8, 9, 11-13, 20-36, and 39-52 and addition of claims 53-82 in the AMENDMENT AND REQUEST FOR RECONSIDERATION dated 1/10/2003 (Paper No. 18) is acknowledged.

3. Newly submitted claims 70, 71, and 73-80 are directed to an inventions that are independent or distinct from the invention originally claimed for because the product and method of claims 70, 71, and 73-79 are directed toward divergent subject matter, specifically, a *coryneform* bacterium which comprises an attenuated lysR1 gene.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 70, 71, and 73-79 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 53-69, 72, 81, and 82 are under consideration in this Office Action.

### *Claim Objections*

5. Claim 72 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Claim 82 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 59, 63, 64, 81, and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass all polynucleotides which hybridize to SEQ ID NO: 1, all polynucleotides comprising 30 to 383 consecutive nucleotides of SEQ ID NO: 1, all polynucleotides comprising at least 30 to 383 consecutive nucleotides of SEQ ID NO: 1, all polynucleotides comprising the full complement of nucleotides 201-1109 of SEQ ID NO: 1, and all polynucleotides which are a full complement of the nucleotide sequence of SEQ ID NO: 1. The specification only discloses SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 3 as representative species of the claimed invention. However, the specification does not provide a written description of any structure to function or activity relationship or the nucleotide sequence that is 5' and 3' of the claimed polynucleotides. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

9. Claim 59 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:2 or an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1, does not reasonably provide enablement for an isolated polynucleotide which hybridizes to SEQ ID NO:1 under stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the

state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claim encompass any isolated polynucleotide which hybridizes to SEQ ID NO:1 under stringent conditions. The specification provides guidance and examples for making a for an isolated polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:2 or an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any isolated polynucleotide which hybridizes to SEQ ID NO:1 under stringent conditions is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotides is enormous and entails screening for a vast number of organisms for the claimed polynucleotide and then determining the biological function, biological activity, or utility of the polynucleotide. Since routine experimentation in the art does not include screening vast numbers of organisms for the claimed polynucleotide, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotide. Without such a guidance, the experimentation left to those skilled in the art is undue.

10. Claims 68, 69, and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of claims 68, 69, and 72 appears to employ a novel gene, vector, and host cell. Since they are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be biblically known and freely available. The requirements of 35 U.S.C. 112, 1st paragraph may be satisfied by deposit of the plasmid and host cell. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmid and host cell should have been made in accordance with 37 C.F.R. 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or

declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(4) the deposit will be replaced if it should ever become inviable.

### *Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph*

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 53-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 53, 58, 59, and 62, the phrase "the activity of SEQ ID NO; 2" renders the claim vague and indefinite because the meaning of the phrase is not known and not defined in the specification and the specific activity is not recited in the claim. Claims 54-57, 60, and 61 which depend from claims 53, 58, 59, or 62 are also rejected because they do not correct the defect of claims 53, 58, 59, 62.

13. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolating or purifying the produced protein.

***Conclusion***

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF